

510(K) SUMMARY

A) Submitter's Name: *Cleveland Medical Devices Inc.*

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E) Preparation Date: November 21, 1996

F) Classification Name: Urine Collector and Accessories

Common / Usual Name: Urine Drainage Valve

Proprietary Name: Liberty Valve™

Classification: Class II The classification number for this device is 89 IRN and is reviewed by the Physical Medicine Panel.

Regulation: 876.5250

a) A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2) a urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device and the paste-on device for incontinence.

b) 1) Class II for a urine collector and accessories intended to be connected to an indwelling catheter.

G) Substantial Equivalence: The design concept of the Liberty Valve is substantially equivalent in design to:

EZMT Valve Co. E-Z Pull Urinary Drainage Valve;

R.D. Equipment Electric Leg Bag Emptier.

H) Description: The Liberty Valve consists of a switch box, a solenoid valve with electrical connection, a fuse, battery leads with wiring, and tubing with the necessary connections for attachment to the leg bag and valve. The device is to be mounted to the wheelchair permanently with the clamps and wire ties provided. The switch box regulates the power from the battery which opens the solenoid valve to allow the urine collection leg bag to drain.

I) Intended Use: The Liberty Valve is intended to allow individuals in a wheelchair to empty their own urine collection leg bag, which may be connected to either an indwelling or non-indwelling catheter, provided the individual possesses the ability to make gross arm and hand movements. Previously such a task required external assistance or unwanted difficulty, thus limiting the individual's independence.

J) Summary of Safety and Effectiveness of Liberty Valve:

The Summary of Safety and Effectiveness on Liberty Valve reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

The Liberty Valve was tested in worst case scenario for possible current leaks. Placed in a supersaturated salt water solution for 2.5 hours, with continuous flushing of same solution through the valve, no part on the valve exhibited a potential, (relative to the negative terminal), and there was no current leaks. This is true for readings taken both in the solution, and from the surface of the valve. With both the internal and external components of the valve tested simultaneously, the absence of electrical activity in the solution confirmed the electrical stability of the Liberty Valve. (This result is achieved through the use of the septum and o-ring at the interface of the valve and connector.)

time(min)	A _i in solution	V _i in solution	A _s on surface	V _s on surface
3	0	0	0	0
13	0	0	0	0
30	0	0	0	0
150	0	0	0	0

The Liberty Valve is similar in operation and function to the E-Z Pull Urinary Drainage Valve of the EZMT Valve Co.

	Liberty Valve	R.D. Equipment Electric Leg Bag Emptier	E-Z Pull Urinary Drainage Valve
<i>1 Valve Operation</i>	Normally closed Opens when activated Automatically closes	Normally closed Opens when activated Automatically closes	Normally closed Opens when activated Automatically closes
<i>2 Valve type</i>	Solenoid	Solenoid	Stretch
<i>3 Switch Operation</i>	Push Button On/off Toggle	Toggle	Pull Tab

K) Bench Testing:

Tests were conducted at 0°C, 23°C and 70°C to determine the range of operation for the Liberty Valve. At all three temperatures, the Valve required less than two minutes to drain 500 mL from a urine collection bag held ten inches above the valve itself. It is advised that the Liberty Valve be used at temperatures between 0°C and 70°C.

Liberty Valve Test Results at Selected Temperatures

Temperature (°C)	0	23	70
Time (min)	1:53	1:49	1:45